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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,188	07/30/2001	Jean-Francois Gestin	98 BA INS SAM	2901

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,188

Applicant(s)

GESTIN ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election with traverse of group V, claims 28-33 with species of compound 13 (AL245) and the use in radioimmunotherapy, in the reply filed on Nov. 9, 2005 is acknowledged. The traversal is on the ground that an examination of all the claims was made in the previous office action. This is not found persuasive because the examination was made with respect to claims 1-18 which have all been canceled. The restriction was made with the newly added claims 19-38 based on PCT rule 13 annex B part 1(f)v. The newly available evidence found in US 5,292,938 or CA 125 indicated the propriety of the restriction.

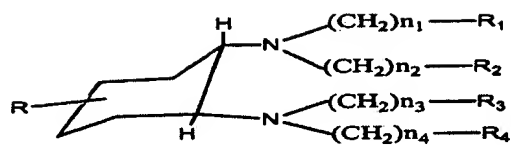
Based on the species election, the scope of examination to the complex is limited to the R is hydrogen compounds. Not only compounds when R is protein, nucleic acid etc. is patentably independent and distinct material for which searches for such material (protein and nucleic acids requires sequence searching) is not coextensive to complexes without biological material. But also, when R is  $\text{NHCOCH}_3$ , the claims finds anticipation by Loussouarn et al. J. Chem. Soc. Perkin. Trans, 1, 1998). Please note that the reference is received for publication in 1997 with anticipatory compound having R being  $\text{NHCOCH}_3$  (see p.238 compound 6 in complex of page 240), thus, a 102(a) and (f) anticipation.

Evidence in the record therefore provided factual support that the groups and the species are independent and patentable distinct inventions. Were they not restricted, then there could have been no patentability of all the claims over Loussouarn 1998 supra.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-33 complex for compounds of formula

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(I)

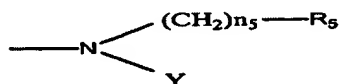
wherein:

-  $n_1$ ,  $n_2$ ,  $n_3$  and  $n_4$ , independently from each other, represent an integer from 1 to 5,

-  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$ , independently from each other, represent :

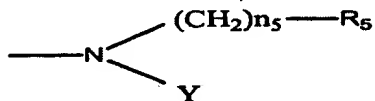
. -COOH,

. -PO(OH)<sub>2</sub>,



wherein  $n_5$  represents an integer from 1 to 5,  $R_5$  represents -COOH or -PO(OH)<sub>2</sub>, and Y represents H or a group -(CH<sub>2</sub>)<sub>n<sub>6</sub></sub>-R<sub>6</sub> in which  $n_6$  represents an integer from 1 to 5, and  $R_6$  represents -COOH or -PO(OH)<sub>2</sub>,

provided that at least one of  $R_1$ ,  $R_2$ ,  $R_3$  or  $R_4$  represents a group



wherein,

- R represents :

Hydrogen.

2. Claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the term “complex” referring to. No description as to the *structure* of this term complex was found in the specification. The formation of the complex was described being resulted from the “association of said radioelement with the COOH and/or PO(OH)<sub>2</sub> groups of said compound (see p.7 specification). The scope of the claims cannot be ascertained because what constitute associate chemically is not understood.

Based on the structural description for the association described for scheme IV and V, the complexes are interpreted to its broadest understanding that the amino groups are stripped of substitutions and the radionuclide will be chelated at the site.

3. Claims 30, 31, 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; as well as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; or in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention.

Please note that for method of radioimmunotherapy, an antibody for the immunotherapy is an element that must be included in such method (see Loussouarn J. Chem. Soc. Perkin trans 1, 1998, recited on 1449). A complex without antibody, i.e. chelating of a compound and a

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radionuclide per se, is useful in selective imaging (see Brechbiel et al. Inorg. Chem.. 35, p.6343 introduction, recited on 1449). The specification provided no description or enablement as to how a process or a complex without any involvement of antigen and antibody interaction can be used for radioimmunotherapy.

Immunotherapy is a highly complexed process involving specific antigen and antibody reactions. Absent of any description of what kind of antigen, how the antibody was produced and introduced, how the radio-portion was included at what stage, one having ordinary skill has been given no "how to". The complexity of the field of immunology requires specific description and enablement for one skilled in the art to practice the claimed method. In absence of any description, example and guidance, the specification offered no support for the claims. Section 112 requires the application itself to inform not for others to find out for themselves. Ex parte Aggarwal 23 USPQ2d 1334; In re Gardner 166 USPQ 138.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. CA 103:97797; Kodama et al. Ca 70:61574; Atoh et al. CA 128:56631 supplemented with O'Shaughnessy et al. CA 139:269680.

Based on the broadest interpretation of the complex as disclosed on page 24, the complexes as disclosed by CA 103, 128 or 70 anticipated the claimed complexes between a compound of claim 19 when it forms a complex of page 24 with a metal ion. The difference between the instant claims and the prior art is that the prior art metal ion are not radioactive.

One skilled in the chemical art would be motivated to prepare the same complexes with a corresponding radio active element of the metal ion because radioactive labeling is routine way of making tracer material for biological use.


The O'Shaughnessy et al. reference provided *evidence* that the element Sm would form complexes with amine compounds in similar manner as the prior art complexes involving Co, Ni etc. through the amine nitrogen. Therefore, with respect to the elected species of a complex of AL245 with Sm153, an obviousness rejection is also applicable.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jan. 31, 2006

  
Celia Chang  
Primary Examiner  
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